Research at NMCP

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Naval Medical Center Portsmouth

NAVY MEDICINE
World Class Care…Anytime, Anywhere

The views expressed in these presentations are those of the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

DISCLOSURE

- Thomas Rieg and all others involved in the development and presentation of this Research Symposium provide the following disclosure information:

"Nothing to disclose"

Objectives

- Naval Medical Research at NMCP
- NMCP IRB Process
- CID Support
- Publication

- Quiz at the end!!

Thinking about Research?

Think

CID

Thinking about Research?

Think

Clinical Investigation Department

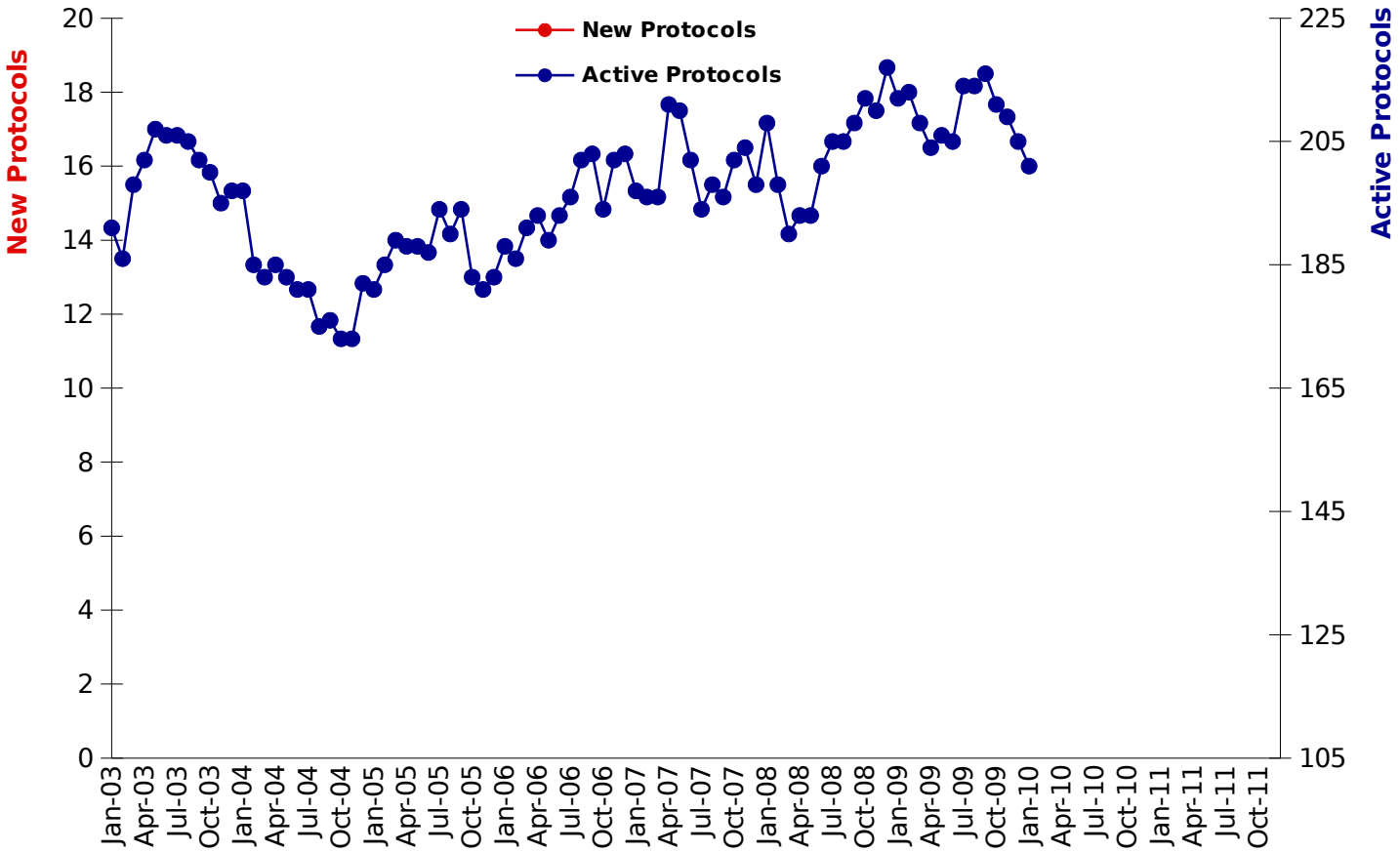
SG Strategic Goals

Tier 1 & Tier 2 Strategic Goals

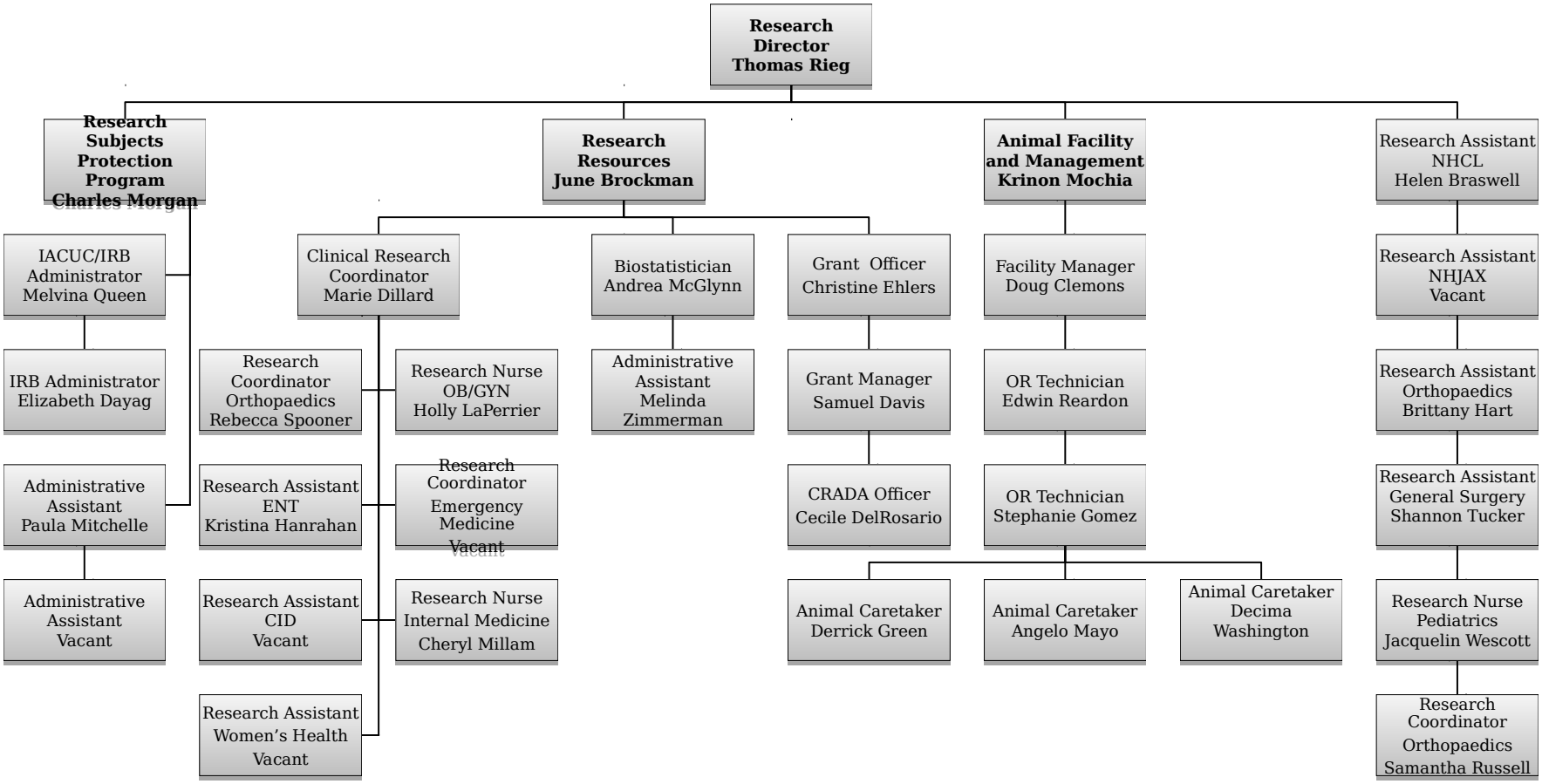
Research and Development
Navy Medicine will conduct relevant research, development, testing, evaluation, and clinical investigations which protect and improve the health of those in our care.

Tier 2 Goals
1. Produce required research products that preserve, protect, treat, rehabilitate, or enhance the performance of Navy and Marine Corps personnel and health care services.
2. Engage in partnerships to enhance efficiencies and project Navy Medicine pertinence in the research and academic communities.
3. Achieve and maintain a national and international reputation as a high-quality, high-performance biomedical research enterprise.

NME Research Protocols

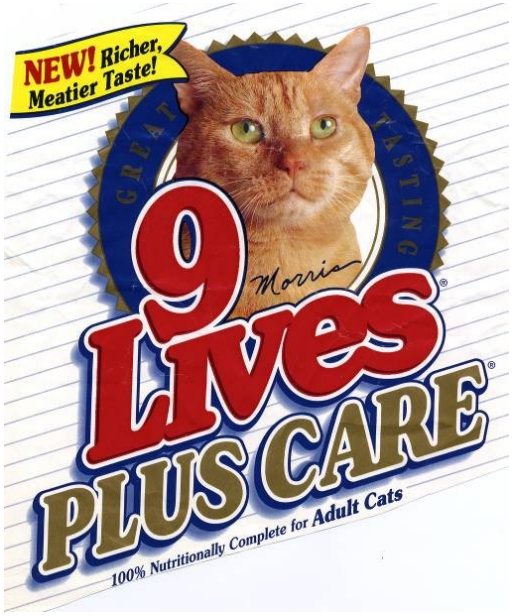


CID Org Chart


Research Director Thomas Rieg
Research Subjects Protection Program Charles Morgan
Research Resources June Brockman
Animal Facility and Management Krinon Mochia
Research Assistant NHCL Helen Braswell
IACUC/IRB Administrator Melvina Queen
Clinical Research Coordinator Marie Dillard
Biostatistician Andrea McGlynn
Grant Officer Christine Ehlers
Facility Manager Doug Clemons
Research Assistant NHJAX Vacant
IRB Administrator Elizabeth Dayag
Research Coordinator Orthopaedics Rebecca Spooner
Research Nurse OB/GYN Holly LaPerrier
Administrative Assistant Melinda Zimmerman
Grant Manager Samuel Davis
OR Technician Edwin Reardon
Research Assistant Orthopaedics Brittany Hart
Administrative Assistant Paula Mitchelle
Research Assistant ENT Kristina Hanrahan
Research Coordinator Emergency Medicine Vacant
CRADA Officer Cecile DelRosario
OR Technician Stephanie Gomez
Research Assistant General Surgery Shannon Tucker
Administrative Assistant Vacant
Research Assistant CID Vacant
Research Nurse Internal Medicine Cheryl Millam
Animal Caretaker Derrick Green
Animal Caretaker Angelo Mayo
Animal Caretaker Decima Washington
Research Nurse Pediatrics Jacquelin Wescott
Research Assistant Women's Health Vacant
Research Coordinator Orthopaedics Samantha Russell

Developing a Research Project

1. Interesting idea ✉ research hypothesis
2. Get the right people involved
   - Research Coordinator, Subject Matter Expert
3. Develop a protocol
4. Discuss with CID statistician
5. Use appropriate CID templates/forms including informed consent document

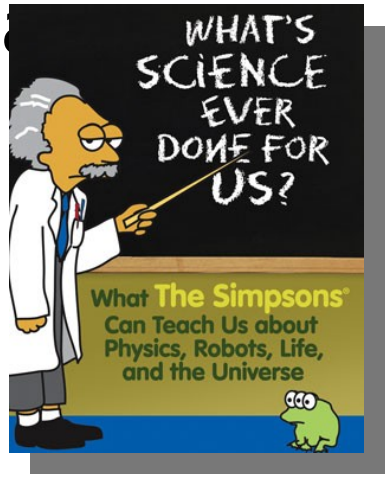


Completing your project

6. CID submits for scientific review
7. CID sends to full IRB or to IRB Chair
   - More guidance likely to be provided prior to approval
8. IRB approval is recommendation
   - CO's signature ✉ start research!!
9. Submit continuing reviews, amendments, adverse events with medical monitor reports as required
10. Submit for completion with manuscript or abstract

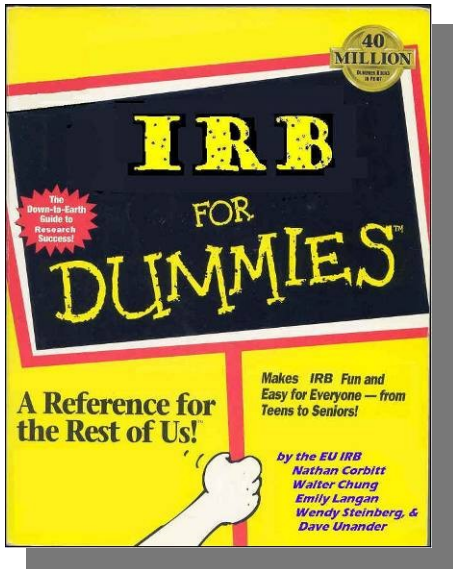
Scientific Review

- DoD Mandated
- Occurs prior to IRB review
- Electronic submission (Exempt & Expedited)
- Scientific Review Committee (Full board)
- Two reviewers within specialty area
- One reviewer outside area
- Volunteers within department
- Forwarded to IRB or returned



The IRB

- Similar to Institutional Animal Car and Use Committee (IACUC)
- Definition
- Regulations
- Membership
- IRB Functions
- Protection of Subjects
- Review of Research



IRB: Love it . . . or hate it

- **Hate it:** Inhibits research, needless regulations and paperwork, long delays and can be intimidating
- **Love it:** Protects subjects, improves quality of research, ensures statistical significance can be met
- Made of up of your colleagues who are doing their best

NME Assurances

- NMC Portsmouth
- NH Jacksonville
- NH Pensacola
- NH Camp Lejeune
- NH Beaufort
- NH Naples
- NH Sigonella
- NHCS Great Lakes
- Naval Health Clinic New England
- Navy and Marine Corps Public Health Center (NMCPHC)
- Naval Special Warfare Group TWO, Little Creek, VA
- Naval Special Warfare Group FOUR, Dam Neck, VA, & Stennis, MS
- Naval Operational Medicine Institute (NOMI)
- COMNAVAIRLANT
- Center for Security Forces, Brunswick, ME
- Christiana Care Health System, Delaware
- Battelle Memorial Institute, Columbus OH
- Geneva Foundation
- Henry M. Jackson Foundation

Research Ethics Violations

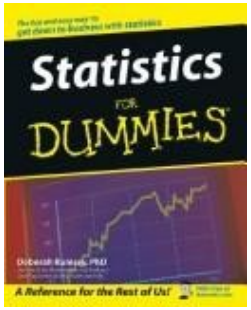
- 45 CFR 46 - DHHS (1981)
  - Known as the Federal Policy or “Common Rule”
- 32 CFR 219 – DoD
- 21 CFR - FDA
  - Part 50 – sets the provisions for ICD
  - Part 56 – sets provisions for the IRB
  - Part 312 – IND Application
  - Part 812 – IDE
  - Part 860 – Medical Device Classification Procedures
- SECNAVINST 3900.39D
- BUMEDINST 6000.12A
- NSHSBETHINST 6000.41B
- NAVMEDCENPTSVAINST 6500.2D
- Local Instructions

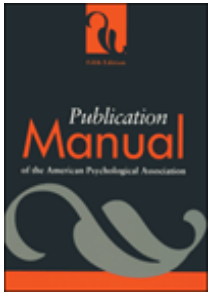
IRB Process Times FY-11

	Days	Range
Scientific Review	18	1-53
To IRB	72	1-188
Approved by IRB	82	6-187
Approval by CO	109	1-115
With Agreement (CRADA)	126	3-773

Research Resources Division

- Study Design Assistance
- IRB Approval
- Data Collection
- Statistical Analysis
  - Pre and Post Study
- Manuscript Completion
- Publication Approval

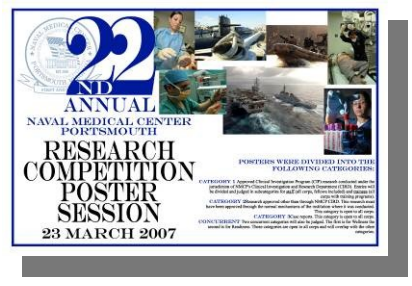


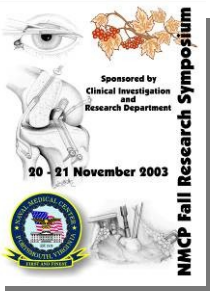


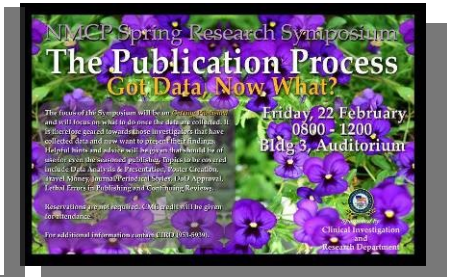
Training

- **Fall Research Symposium:** Conducti Research (Sep)
- **Spring Research Symposium:** Getti Published (Feb)
- **Annual Research Competition**
  - Poster Session & Oral Session (Mar & Apr)
  - 3 Categories
  - Navy-Wide Competition (May)
- **Lectures/Courses/Workshop**

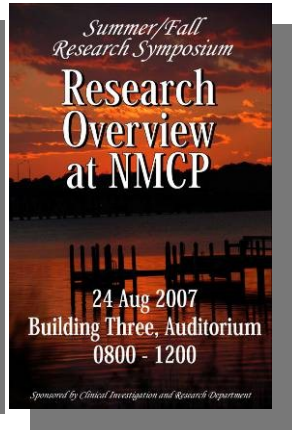
Research Symposium
Conducting Research in NMP
Wednesday, 16 November 2011
0809 - 1300
The Symposium is designed to provide investigators with an overview of the research process. Topics will include issues such as:
Why should I Conduct Research?
What Types of Research Designs are Available to me?
Why Perform a Literature Search?
How can I receive Funding for my Research?
Why should I be Concerned about Ethics when Conducting Research?
What is an IRB and how do I complete the IRB Application Process?
Sponsored by NMCP, Clinical Investigation Department, NMC







NAVAL MEDICAL CENTER PORTSMOUTH
24th Annual
RESEARCH COMPETITION POSTER SESSION
20 MARCH 2008
POSTERS WERE DIVIDED INTO THE FOLLOWING CATEGORIES:



Funding Sources

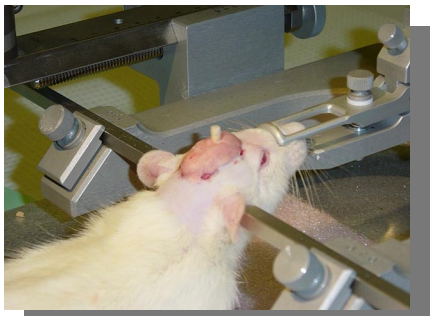
- NMCP Sources (OPTAR)
- External Grants
  - MOU, CRADA, MOA, ISSA, *etc.*
- Gifts
- Non-Profit Intermediaries
- BUMED SG Fund
- Grants Writer

Some Funded Studies

Title	Primary Investigator // Department	Funding Source	Total Amount
The Effects of Hypothermia and Negative Pressure on Bacteria Proliferation in an Open Fracture in Goats	**LT Jarod Goodrich, MC, USN (Orthopaedics)**	**BUMED / WII**	**$120,780**
Retrospective Administrative Limited Duty Outcome Review	**CAPT Gregg Ziemke, MSC, USN (Physical Therapy)**	**BUMED / CIP**	**$256,365**
Outcomes following Cervical Fusion Versus Cervical Arthroplasty: A Cadaveric and Human Assessment	**LCDR Jason Zook, MC, USN (Orthopaedics)**	**BUMED / CIP**	**$141,015**
Pilot Study on the Effect of Group Interpersonal Psychotherapy on Depressed Spouses of Active Duty Members who are or have been deployed to a Combat Theater	**CAPT Gail Manos, MC, USN (Orthopaedics)**	**NMCP Commander's Grant**	**$4,500**
The Effect of Localized Cooling on Systemic Body Temperature in Humans	**LT Catherine Rapp, MC, USN (Orthopaedics)**	**NMCP Commander's Grant**	**$3,000**
Dynamics of methicillin-resistant *Staph. aureas* colonization and its correlation with skin and soft tissue infections in personnel deployed on U.S. navy ships	**CDR Jennifer Curry, MC, USN (Infectious Diesaes)**	**GEIS Global Emerging Infections Surveillance**	**$155,970**

DoD Animal Care & Use Programs

- DoD animal use is critical to developing vaccines, drugs, and therapies to protect, sustain, and treat service men and women
- To prevent the fielding and use of ineffective or dangerous treatments
- Use animal models when human use protocols are simply not possible



Responsibilities

- MAJ Krinon Moccia, VC, USA
- Laboratory animal colony management and husbandry
- Veterinary preventive medicine, medical care, and pre/postoperative care
- Consultation in protocol development
- Investigator training
- Oversight of all animal use
- Ensure regulatory compliance
  - Reporting requirements to DoD, USDA, AAALAC, *et al.*

Recent Animal Protocols

- Research Protocols
  - Chinchilla Ear Prosthesis and Tympanic Membrane Repair
  - Rat Blast Injury Prevention
  - Mice Anaphylactic Shock
  - Wound Cooling in Goats
  - Vasopressin for Hemorrhagic Shock in Pigs

- Teaching Protocols
  - Microsurgery Course using Rats
  - ER Trauma - Quick-Clot using Pigs
  - Pediatric Intubations using Ferrets

Publications FY-11

- Total = 246
  - Staff = 117
  - Trainee = 129
  - Conferences = 172
  - Publications = 73

- 79 Conference travel paid by CID for $106K

21 PubMed Publications

Petilon J, Roth J, Hardenbrook M.	Results of Lumbar Total Disc Arthroplasty in Military Personnel.
Crum-Cianflone NF, Huppler Hullsiek K, Roediger M, Ganesan A, Patel S, Landrum ML, Weintrob A, Agan BK, Medina S, Rahkola J, Hale BR, Janoff EN.	A Randomized Clinical Trial Comparing Revaccination with Pneumococcal Conjugate Vaccine to Polysaccharide Vaccine among HIV-Infected Adults.
Kuhn JJ, Clenney T.	The association between semicircular canal dehiscence and Chiari type I malformation.
Lutgendorf M, Busch J, Magann EF, Morrison JC.	Domestic violence screening in a military setting: provider screening and attitudes.
Beute TC.	The use of a topical antihistamine in the treatment of raised linear bands of infancy.
Wingert N, Tavakoli H, Yoder E.	Acute hepatitis and personality change in a 31-year-old man taking prohormone supplement SUS500.
Maroules CD, Bhasin M, Sposato J, Whiting E, Mitchell E.	Evaluation of cor triatriatum dexter with use of 64-slice multidetector computed tomography.
Schofer JM, Nomura JT, Bauman MJ, Sierzenski PR.	Prospective durability testing of a vascular access phantom.
Fitzpatrick J, Speakman J, Kapfer SA, Holston AM.	Transplacental passage of the non-ionic contrast agent iopamidol in twins.
Miller MB, Weber DJ, Goodrich JS, Popowitch EB, Poe MD, Nyugen V, Shope TR, Foster DT, Miller JR, Kotch J.	Prevalence and Risk Factor Analysis for MRSA Nasal Colonization in Children Attending Child Care Centers.
Kuhn JJ, Lassen LF.	Congenital incudostapedial anomalies in adult stapes surgery: a case-series review.
Mentler E, Mann K, Earley A, Lucha P.	High incidence of acute urinary retention associated with immediate catheter removal after laparoscopic Nissen fundoplication.
Antevil JL, Carroll CG, Roberts PF, Johnston MG, Strange RG.	Myasthenia gravis--an unexpected cause of respiratory failure and reversible left ventricular dysfunction after cardiac surgery.
DiCarlo-Meacham A, Dahlke J.	Atrial fibrillation in pregnancy.
Gist RS, Sullivan M, Serianni RP.	Management of substance abuse in the hospital setting.
Lee RU, Stevenson DD.	Aspirin-exacerbated respiratory disease: evaluation and management.
Duplessis C, Rascona D, Cullum M, Yeung E.	Salivary and free serum cortisol evaluation.
Nguyen HD, Galitz MS, Clarke DD.	Visual Vignette
Salzbrenner S, Breeden A, Jarvis S, Rodriguez W.	A 48-Year-Old Woman Primigravid via In Vitro Fertilization With Severe Bipolar Depression and Preeclampsia Treated Successfully With Electroconvulsive Therapy.
Gresens, J., Rhodes, D., Smith, J., Gentry, A.	Evaluation of Possible Association between Statins and Abnormal Esophageal Motility
Bose DA, Assel BG, Hill JB, Chauhan SP.	Maintenance tocolytics for preterm symptomatic placenta previa: a review.

Medical Editing

- **“There were four things that we did which led to the subject’s death.”**
- Changed:
- **“Four changes resulted from this case.”**

Medical Editor

- The Medical Editor will assist with
  - Organization
  - Grammar, clarity, etc.
  - Journal specific formatting
- Get the Editing Request Form from the CID web page at

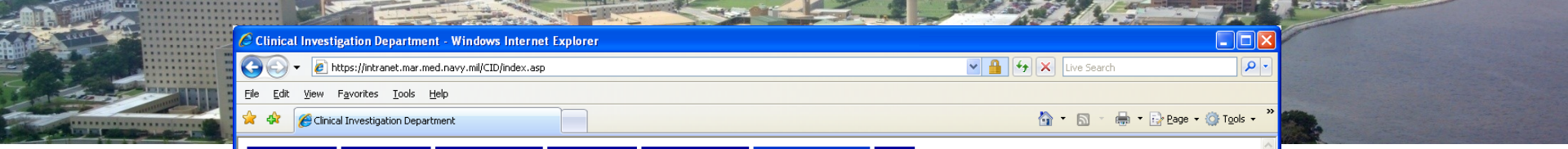
  https://intranet.mar.med.navy.mil/CID/index.asp
  - Complete the form
  - Email it and manuscript to June.Brockman@med.navy.mil

“Authored Works”

- Any written document, both personal and professional, intended to be published to the general public (brochure, book, manuscript, screenplay, magazine, newsletter, etc.,) or oral presentation related to official duties

twitter Find us on Facebook

- Includes any authored work that is to be transmitted via the internet, mass broadcast, or mass e-mail where the general public *may* be able to obtain the authored work
- Contact the Ms. June Brockman for guidance if you believe the work is not in conjunction with official duties



Clinical Investigation Department - Windows Internet Explorer

https://intranet.mar.med.navy.mil/CID/index.asp

File Edit View Favorites Tools Help

Clinical Investigation Department

NMCP | Directory | Watchbills / POD | News / Info | Features | Documents | FAQ

Welcome to Intranet
The Charette Health Care Center

Wednesday, November 09, 2011

Search the Intranet: Go

Information Technology Support

Intranet > CID

Clinical Investigation Department

Phone: (757) 953-5939 **Fax:** (757) 953-5298
Building 274, 1090 Edwin May Road

RESEARCH APPLICATION FORMS

Research Application Forms

MEETING DATES & SUBMISSION DEADLINES

Institutional Review Boards (IRBs)
Institutional Animal Care and Use Committee (IACUC)

INFORMED CONSENT PROCEDURES

Step-by-Step Consent Procedures

RESEARCH TRAINING

CITI Program Training - Mandatory
Supplemental Research Training

ANIMAL RESEARCH

INVESTIGATION RESOURCES

CID FAQ
Biosketch Template
CV Template
Curriculum Vitae Instructions
Library Research Toolkit
CRADA Information Form
Research Assistance Request Form

CID NEWSLETTERS

Jun 2011
Dec 2010
Jun 2010

PUBLICATION APPROVAL

Form to Request Approval
BUMED Instruction
BUMED PAO Request
NMCP Instruction

Travel Funding

MEDICAL EDITING

Edit Request Form

CONFERENCES/SYMPOSIA

Fall 2010 Research Symposium

RESEARCH LINKS

NMCP Research Coordinators
CID Research Links

EMERGENCY USE OF A DRUG

NAVMEDCENPTSVA 6710.10C
21 CFR Part 312.36-41 Emergency Use of a Drug

2012 ACADEMIC RESEARCH COMPETITION

ARC Announcement
ARC Abstract Submission Form

STAFF

Last Updated: 13-Oct-2011

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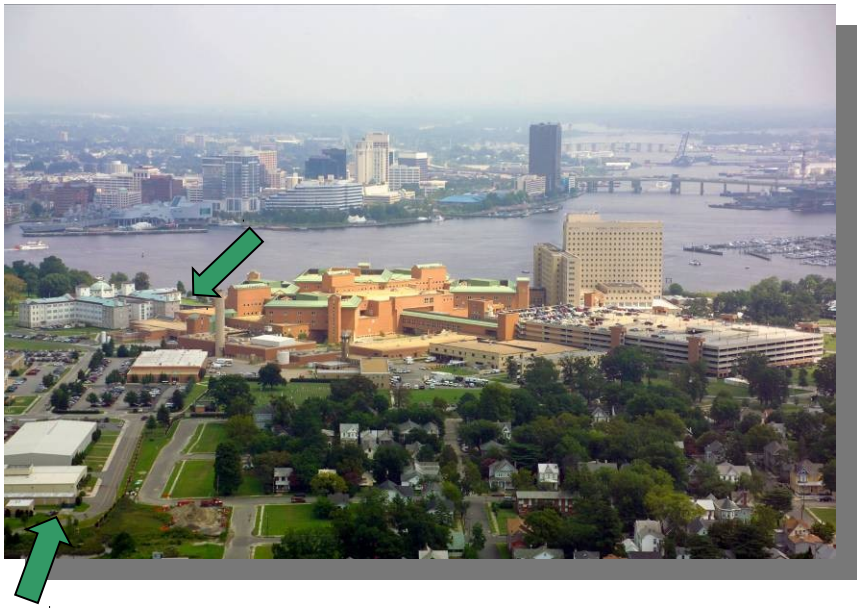
Trusted sites 100%

Location, Location, Location

- NMCP
- Building 274
- Building 1, First Deck, Rm C128



Thinking about Research?

?

Thinking about Research?

Think **CID**

Questions?
Comments?

Call CID: 757-953-5939

Email me: thomas.rieg@med.navy.mil